REMARKS

Claims 18-44 and claims 47-50 have been amended. Claims 45-46 have been cancelled. New claims 51 and 52 have been added. All amendments and cancellations are made without prejudice or disclaimer.

The amendments and new claims find support in the previous claims and the specification. Specifically, the phrase in claim 18, "and is free of fatty acid esters of glycerine," has been deleted as suggested by the examiner. Additionally, the term "fat soluble" has been added to claim 18 as supported in the specification paragraph [0015]. Claim 18 has been further amended as a matter of form regarding the recitation of the particle size and the preamble. Claims 19-21 have been amended to clarify antecedent basis. Claim 21 has been amended to delete the recitation of the particle size, as suggested by the Examiner. Claim 22 has been amended to delete the phrase "and is free of fatty acid esters of glycerine" as suggested by the examiner and has been further amended as a matter of form regarding the recitation of the physical properties of the silica and regarding the preamble. Claims 23-25 have been amended to clarify antecedent basis. Claim 26 has been amended as a matter of form regarding the recitation of the particle size. Claims 27-28 have been amended to clarify antecedent basis. Claim 29 has been amended to delete the phrase "and is free of fatty acid esters of glycerine" as suggested by the examiner and has been further amended as a matter of form regarding the preamble and the recitation of the physical properties of the silica. Claim 30 has been amended to remove the phrase "A United States pharmacopoeia,

food chemical codex, or GRAS supplement" as suggested by the examiner and replaced with the term "vitamin powder," which finds support throughout the specification. Claims 31-44 and claims 47-50 have been amended as a matter of form to clarify antecedent basis. Newly added claims 51-52 find support in previous claims and in the specification, e.g., paragraph [0015]. It is submitted that no new matter has been added to the instant application. Claims 18-44 and claims 47-52 are currently pending. Claims 18-50 have been rejected.

A. Rejection of claims 18-50 under 35 U.S.C. § 112

Claims 18-50 stand rejected under 35 U.S.C. § 112 for assertedly lacking enablement and for not complying with the written description requirement. It is noted that claims 18-44 and claims 47-50 have been amended, and claims 45-46 have been cancelled. Specifically, it is asserted that the scope of enablement only extends to tocopherols. Applicants respectfully disagree.

As an initial matter, the *prima facie* burden is on the USPTO to demonstrate that the claims are not enabled under 35 U.S.C. § 112 (MPEP § 2164.04). Here no evidence or references have been presented by the USPTO to indicate that the claims should not be entitled to the fully claimed scope. Applicants have provided numerous examples in the specification that support the claims. There is no requirement that examples of all of the embodiments in the claimed range be set forth. Thus, the *prima facie* case is not met.

In addition, even if the *prima facie* burden could be met, it is rebutted by the Declaration of Charles A. Morris which is attached (hereinafter, "the Declaration"). The

Declaration demonstrates that free-flowing characteristics can be imparted to compositions other than tocopherols, such as, for example, dry vitamin D_3. Further, it states that "one of ordinary skill in the art would understand that various vitamin compounds could be added to or substituted for the tocopherols (e.g., vitamin E) compositions of the present invention to provide free-flowing characteristics, even though the selected vitamin compound may be solid, or have different structures, characteristics, or stabilities from vitamin E, without the need for unobvious contributions or for undue experimentation." As such, these data and the Declaration prove that the claimed compositions and methods are enabled for the entire scope of vitamins. Thus, withdrawal of the rejection is respectfully requested.

To the extent that the phrase "free of fatty acid esters of glycerine" is objected to for lacking support in the specification, Applicants first note that this phrase negatively limits the claim to the compounds taught in the specification. Negative limitations are allowed where the limitation is used to distinguish an element that the examiner cited in a prior art reference rejection and the limitation is disclosed but not literally recited in the specification. As the MPEP section 2173.05(i) states "a lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. Ex parte Parks, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993)." Further, MPEP section 2163.07 states that "(a) [by] disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or

advantage without introducing prohibited new matter. In re Reynolds, 443 F.2d 384, 170 USPQ 94 (CCPA 1971); In re Smythe, 480 F. 2d 1376, 178 USPQ 279 (CCPA 1973)." Thus, the use of the element in claim 26 is not new matter because it describes a property present in the claimed compositions as originally filed. However, in order to expedite prosecution, Applicants have removed the phrase from claims 18, 22, and 29. Thus, withdrawal of the rejection of claim 26 is respectfully requested.

B. Rejection of claims 21 and 30 under 35 U.S.C. § 112

Claims 21 and 30 are rejected as being assertedly indefinite under 35 U.S.C. § 112. Claims 21 and 30 have been amended to further clarify the scope of the claims. Specifically, the reference to the particle size in claim 21 has been deleted. Additionally, the reference to "A United States pharmacopoeia, food chemical codex, or GRAS supplement" has been deleted from claim 30. Thus, withdrawal of the rejections is respectfully requested.

C. Rejection of claims 18-50 under 35 U.S.C. § 103(a)

Claims 18-50 are rejected under 35 U.S.C. § 103(a) as being assertedly obvious in light of Schmidt et al. (U.S. Patent No. 4,486,435; hereinafter the '435 patent) in combination with Schmidt (U.S. Patent No. 4,603,143; hereinafter the '143 patent).

As an initial matter, claims 18, 28, and the claims that depend therefrom recite vitamins at concentrations of between about 65 to about 80 weight percent (much higher than that taught by the cited references). Additionally, all claims are directed towards having the silica particle size of about 40 to 50 microns. To establish *prima*

facie obviousness, all claim elements must be taught or suggested by the combination of prior art. MPEP § 2143.03. The cited references do not render obvious the claims 18-50 because the percentage of vitamin and the size of the silica particles are not disclosed or suggested in the cited references. As such, these references do not implicitly or explicitly disclose each and every element of the claims either alone or in combination.

Furthermore, there is no teaching, suggestion, or motivation to combine the cited references. In fact, the '143 patent teaches away from adding cornstarch and silica. Specifically, it is stated in the '143 patent that "the various processes of the prior art which involve the use of water and emulsifiers, such as gelatin and starch...are unnecessary to the process of the [Schmidt] invention." U.S. Patent No. 4,603,143, column 2, lines 39-42. Accordingly, the '143 patent is not properly combinable with the '435 patent to render obvious claims 18 to 50.

In addition, the '435 patent teaches the use of corn starch but only in the context of ultrafine aerosolized silica for encapsulating spray dried particles of riboflavin and starch (U.S. Patent No. 4,486,435; c.5, ln.65). Moreover, the '435 patent teaches that such silica particles must be "ultrafine" to encapsulate the riboflavin and starch. *Id.* at c. 4; ln. 21, and c. 4, lines 24-29.

The term "ultrafine" is defined as silica having a particle size of about 0.01 microns to about 0.04 microns. *Id.* at c. 3, lines 33-36. In contrast, the claimed particle size (about 40 to 50 microns) is >3000 times larger than that taught in the '435 patent. Indeed, in its final form, the silica component that encapsulates the riboflavin and corn starch of the '435 patent does not form particles as recited in the claims, but rather

forms a coating. In fact, the silica encapsulated particles of the '435 patent are clearly distinguishable as conventional spray dried particles that lack one or more of the disclosed advantages of the claimed compositions (see the specification, paragraph [0004]). Thus, neither reference teaches or suggests a free-flowing composition where both starch and silica of the claimed size ranges are combined. As such, there is no teaching by either reference as to how to combine the claimed elements so as to provide free-flowing characteristics to the claimed composition, and, thus, the rejection is respectfully obviated.

For at least the reasons discussed above, reconsideration and withdrawal of the rejections of claims 18-50 for obviousness over the '143 patent and the '435 patent are requested. Claims 18-50 define over the prior art of record and are in proper form for allowance. Applicants respectfully request allowance of claims 18-52.

If the undersigned can be of assistance to the Examiner regarding any of the above, please contact the undersigned at the number set forth below.

Respectfully submitted,

3/7/06
Date

C. Allen Black
Reg. No. 53,835
Customer No. 41,835

KIRKPATRICK & LOCKHART Nicholson Graham LLP
Henry W. Oliver Building
535 Smithfield Street
Pittsburgh, Pennsylvania 15222

Telephone: (412) 355-6319
Facsimile: (412) 355-6501